1.0 PURPOSE

This policy provides guidance to Principal Investigators and research personnel for the development of protocol documents for clinical trials that are funded and/or sponsored by the Division of Acquired Immunodeficiency Syndrome (DAIDS).

2.0 SCOPE

This policy applies to all clinical trials funded and/or sponsored by DAIDS that are conducted outside of the DAIDS-sponsored HIV/AIDS Clinical Trial Networks.

It does not apply to clinical trials developed within or in collaboration with the HIV/AIDS Clinical Trial Networks that use network-specific templates for protocols and associated documents.

This policy can be superseded by specific terms of award included in Notice of Grant Awards, Statement of Work in National Institute of Allergy and Infectious Diseases (NIAID) contracts, or specific requirements identified in NIAID Program Announcements, Requests for Applications or Requests for Proposals.

3.0 BACKGROUND

A protocol is a document that describes the objective(s), design, methodology, statistical considerations, and organization of a clinical trial. The protocol document should provide unambiguous direction to promote consistent and reliable study implementation, conduct and analysis and facilitate participant safety throughout.

4.0 DEFINITIONS

See DAIDS glossary.

5.0 RESPONSIBILITIES

The Principal Investigator is responsible for ensuring that the protocol document developed by the team and submitted to DAIDS for review and approval is complete and consistent, methodologically sound, and directs study conduct to be in accord with all applicable regulations, NIH and DAIDS policy. Protocol documents for clinical trials that will be conducted in a single location must also reflect awareness of and compliance with local laws and regulations.

DAIDS Scientific Review Committees (SRCs) are responsible for the review, comment and approval or disapproval of all clinical trials funded and/or sponsored by DAIDS before the protocol is submitted for DAIDS-required final reviews/sign-offs (full regulatory review, Medical Officer, and final DAIDS sign-off) prior to implementation.

The DAIDS Regulatory Affairs Branch is responsible for the full regulatory review of the protocol. If the protocol will be registered with the DAIDS Protocol Registration Office, then full regulatory review is required.

The DAIDS Medical Officer is responsible for the review and approval of the final version of the protocol after SRC and full regulatory review, if applicable. The DAIDS Medical Officer is responsible for providing any comments upon completion of the review. The DAIDS Medical Officer comments must be addressed before final DAIDS sign-off.

The DAIDS-Regulatory Affairs Branch is responsible for facilitating the final DAIDS sign-off of the protocol and informed consent after DAIDS Medical Officer review and approval.

6.0 POLICY

6.1. The clinical trial protocol should contain all essential information required to implement, plan and conduct a study and should be organized so as to allow ready access to relevant information. The clinical trial protocol document must reflect awareness of and compliance with the following:

6.1.1. All clinical trials funded and/or sponsored by DAIDS must be designed and conducted in compliance with U.S. Code of Federal Regulations 45 CFR 46 and Subparts and the International Conference on Harmonisation, Good Clinical Practice (ICH E6).

6.1.2. Clinical trials submitted to the U.S. Food and Drug Administration (FDA) for review must be conducted in accordance with the applicable FDA regulations.

6.1.3. All human subjects research funded and/or sponsored by DAIDS must comply with all applicable laws and regulations at clinical research sites.

6.1.4. NIH, NIAID, and DAIDS have specific policy and guidance directing particular aspects of study development, implementation, safety monitoring and oversight, analysis and publication.

6.2. The DAIDS Guidance for Protocol Documents identifies specific content areas for clinical trials, identifies other regulatory and guidance documents that should be consulted during protocol development, and specifies the level of detail that must be incorporated in the primary protocol document. It does not require use of a specific format. This document is reviewed periodically and updated as necessary to maintain currency with accepted practices, policy, and regulations.

7.0 REFERENCES

U.S. Code of Federal Regulations, Title 45, Part 46, Subparts B, C, and D.
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guideline
http://www.fda.gov/oc/gcp/guidance.html

U.S. Code of Federal Regulations, Title 21, Parts 11, 50, 56, and 312
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

NIAID Clinical Terms of Award
http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at: NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:
http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm

The signed original is maintained in the OPCRO policy office.

10.0 CHANGE SUMMARY

Version #	Date	Replaces	Date of Revision	Rationale for Revision/Retirement
2.0	20 DEC 06	V 1.0	20 DEC 06	DAIDS Final Review
1.0	14 JUL 06	N/A	N/A	N/A

11.0 APPENDICES

Appendix 1 – DAIDS Protocol Guidance for Protocol Documents

12.0 APPROVAL

	Signature	Program/Branch	Date
Authorized By:			December 20, 2006
	Richard Hafner, MD Director	Office for Policy in Clinical Research Operations (OPCRO)	